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Epstein

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[54]	BALANCING APPLIANCE FOR FOOTWEAR
	ITEM

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patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: 09/096,946

[22] Filed: Jun. 12, 1998

Related U.S. Application Data

[60] Provisional application No. 60/058,828, Sep. 15, 1997.

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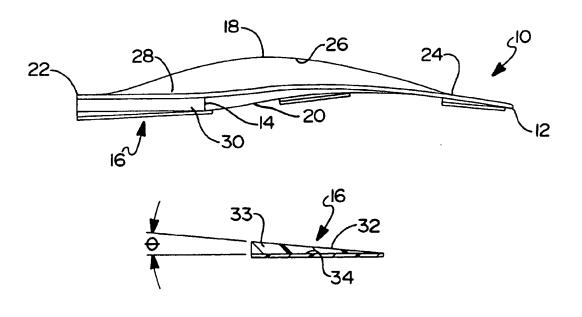
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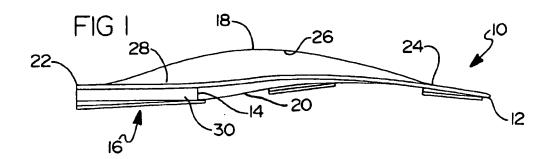
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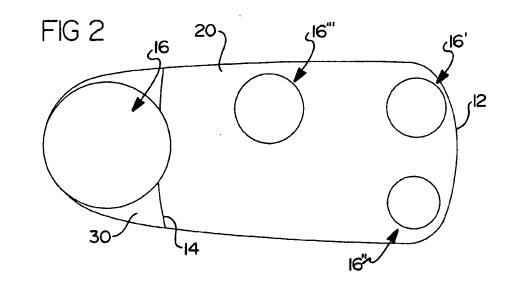
57] ABSTRACT

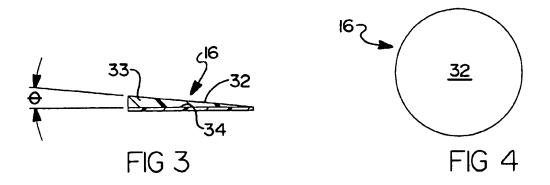
A balancing disc or appliance for use in with a shoe insole, or biomechanical device, such as an ankle or foot brace, for balancing the gait of a user is defined by a substantially circular disc or body element having a top surface and a bottom surface. The top surface and the bottom surface are angularly inclined with respect to each other in an angle ranging from about 2° to about 6°. Optimally, an adhesive is deposited onto one of the surfaces for facilitating affixation of the disc to an insole or similar orthotic device. The disc is, preferably, formed from a flexible material. Since the device is substantially circular in nature, it may be rotated about a vertical axis through a 360° arc to facilitate minute adjustments in the balance of the user.

2 Claims, 1 Drawing Sheet









BALANCING APPLIANCE FOR FOOTWEAR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a completion application based upon co-pending U.S. provisional patent application Ser. No. 60/058,828, filed Sep. 15, 1997 for "BALANCING DISC FOR AN ORTHOTIC FOOT DEVICE," the disclosure of which is hereby incorporated by reference.

STATEMENT REGARDING FEDERALLY FUNDED RESEARCH

Not Applicable.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention involves the field of foot devices. Even more particularly, the present invention involves the field of orthotic foot devices used in chiropracty, physical therapy, orthopedics, osteopathy, and general health care. More particularly, the present invention concerns a balancing disc for use with shoes or orthotic foot devices.

2. Prior Art

Orthotic foot devices, or "orthotics", are used as inserts into footwear to give a user enhanced biomechanical balance and weight distribution during both standing and ambulation. Orthotic foot devices may be either medically prescribed to a precise configuration or an "off the shelf" item which are emplaced within a shoe or other footwear items. Typically, such orthotics comprise a plate in the shape of a plantar part of a human foot plus optional additions, such as wedges, which are secured to the plate, anterior or posterior or both, to create proper alignment and balance of skeletal and muscular body components, thereby providing enhanced balance and weight distribution to the user.

Heretofore, in practice, once installed in a footwear item in attempting to effect proper balance and weight distribution, a skilled technician or practitioner usually would make adjustments to either or both the posterior and anterior areas of the orthotic devices by emplacement of wedges in correct orientation. This is a time consuming task, because of the minute corrections necessary to be made. It is to be, thus, appreciated that there has not been a simple and convenient way for making these necessary adjustments.

The present invention, as detailed below, provides a universal device appliance or balancing disc for providing balance and weight distribution adjustment which is easily 50 integrated with existing orthotic foot devices as well as into other footwear items or devices. In accordance herewith, there is provided a wedge-shaped circular disc, which is particularly adapted to be securable to an orthotic plate in a plurality of incremental orientations through a 360° arc in 55 both the posterior and anterior portions of the orthotic device to provide the requisite adjustment for effecting proper balance and weight distribution. Similarly, the present appliance may be used in conjunction with insoles or be directly attached to a footwear item such as a shoe, sandal, etc. 60

SUMMARY OF THE INVENTION

The present balancing disc for an orthotic foot device which generally comprises:

a substantially circular member having a top surface and 65 a bottom surface, the surfaces being angularly inclined with respect to each other.

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The balancing disc hereof has its top surface and bottom surface angularly inclined with respect to each other by an angle θ . The angle θ will, generally, range from about 2° to about 6° .

The angular inclination enables compensation for balance, depending upon a user's foot.

Ordinarily, the disc hereof is placed upon a heel portion of an orthotic device, such as an insole, but may be placed directly over the heel or other portion of a shoe or in another position on the orthotic device.

Also, a plurality of the devices hereof may be disposed about an insole at appropriate positions.

The present device may be made from any suitable material, such as a flexible rubber, synthetic resinous material or the like.

Additionally, an adhesive may be deposited onto the top surface of the disc to facilitate the securement thereof to the insole or shoe.

Also, from a commercial standpoint, a plurality of these disc's may be packaged as a kit with the plurality having various angles of inclination between the top and bottom surafaces thereof.

For a more complete understanding of the present invention, reference is made to the following detailed 25 description and accompanying drawing. In the drawing, like reference characters refer to like parts throughout the several views, in which:

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side view of an orthotic foot device deploying the balancing disc of the present invention;

FIG. 2 is a bottom view of the orthotic foot device of FIG. 1 with the disc in place;

FIG. 3 is a side view of the disc hereof; and

FIG. 4 is a top plan view of the disc hereof.

DETAILED DESCRIPTION OF THE EMBODIMENTS

With more particularity, and with reference to the drawing, there is depicted an orthotic foot device or orthotic device, generally, denoted at 10 having a balancing disc of the present invention secured thereto and which is, generally, denoted at 16.

In a preferred utilization hereof, the present invention is used with either an extrinsically posted heel cup orthotic device or a flat heel cup orthotic device. Both the flat heel cup type and posted heel cup type of devices are well-known and commercially available, one source being sold under the trademark EVER-FLEX by Ever-Flex, Inc. of Lincoln Park, Mich.

Additionally, the present disc may be used intrinsically in an anterior portion or extrinsically posted orthotic device, 55 both laterally and/or medially of either an intrinsically or extrinsically posted device. Clearly, the disc hereof may be used for both the anterior and posterior portions of the orthotic device, as needed. Likewise, the present invention may be deployed on a flat insole or may be directly emplaced within a footwear item, such as a shoe, sandal, etc.

As shown in the drawing, and with reference to the utilization of the disc hereof in conjunction with an orthotic device, and as is known to those skilled in the art to which the present invention pertains, the typical orthotic device 10 includes a plate or sole plate 12 made of a flexible rigid or semi-rigid material, such as a foam, leather, steel, plastic or the like. Herein for illustrative purposes, the orthotic device



has an intrinsically posted heel cup portion depicted in the drawing. As shown, the plate 12 has a first or top or foot-engaging surface 18 and a second or bottom or footwear-engaging surface 20 opposite the first surface 18. The plate 12 and, particularly, the first surface 18 thereof is 5 shaped to the sole of a human foot, with curvatures, as appropriate. The plate 12 comprises a posterior portion 22, an anterior portion 24, and an arch portion 26 between and connecting the posterior portion 22 and the anterior portion

Clearly, the disc hereof may be used for both the anterior and posterior portions of the device, as needed.

In use, a post 14, made of any suitable rigid, flexible or semi-flexible material, as required, including synthetic rubber, foam, etc., and the like, may be secured to the second or bottom surface 20 of the plate 12 about the posterior portion 22. The post 14 has a first surface 28 and a second surface 30 opposite the first surface. The first surface 28 is shaped to snugly overlie the posterior portion 22 of the plate 12 at the second surface 20 thereof. The second surface 30 20 of the post 14 is, usually, substantially flat or planar. The post 14 is attached to the plate 12 at the posterior portion 18 thereof by any suitable means, such an adhesive or the like.

combination of the plate 12 and the post 14 did not effect the desired result, minute adjustments were accomplished with rectangular-shaped shims or wedges or similar devices. The present disc 16 obviates this, as detailed below.

The disc 16 hereof is a substantially circular solid wedge 30 invention are desired to be protected. member made of either rigid, semi-flexible or flexible material, such as plastic, rubber, synthetic rubber or the like, as required, prescribed and/or desired.

The disc 16 has a first surface 32, a second surface 34, opposite the first surface 32, and a side wall 33 integrally 35 formed with the first surface 32 and the second surface 34. The first surface 32 and the second surface 34 are each substantially circular planar surfaces. The first surface 32 is angularly inclined with respect to the second surface 34 by an angle 0, which generally ranges from about 2° to about 6° . 40 Thus, the disc 16 defines a circular wedge or shim.

The first surface 32 of the disc 16 may be attached to either the post 14 or the plate 12, or both, by any suitable means, such as an adhesive or the like. Because the disc 16 to provide the minute adjustments prerequisite for imparting proper weight distribution and balance to the user. Similarly, and as shown in FIG. 2, one or more discs 16 may be

deployed on the plate and/or the heel cup portion of the orthotic 10 to provide the necessary adjustment for a particular user. For example, one disc 16 may be deployed on the posterior portion and one or more discs 16', 16", etc., on the anterior portion. The locations and orientations of discs 16 on a given plate 12 and/or heel cup portion are determined on a case-by-case basis by a skilled practitioner, based on the balancing needs of an individual user. The disc 16 may, likewise, have any suitable diameter as dictated by the orthotic device 10 and/or post 14 to which it is to be secured. Similarly, in a commercial form, the present disc 16 may be packaged as a kit wherein a pluality of discs have varying angles of inclination between the prescribed ranges.

As noted hereinabove, the present disc may be disposed 15 directly on a footwear item, also, by placing it inside a shoe, sandal, etc., at the appropriate position or on a planar insole.

Further, the present device or disc may be used in conjunction with a biomechanical device such as an ankle brace, a foot brace, a combined ankle and foot brace and the like, where stabilization of the heel is required. The device hereof may be directly incorporated into such a brace with provision for access thereto for adjustment being provided, or may be used as a separate element in conjunction therewith.

While the invention has been illustrated and described in As noted above, heretofore, if the plate 12 and/or a 25 detail in the drawings and the foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described fully and that all changes and modifications that come within the spirit of the

> Having, thus, described the invention what is claimed is: 1. A kit of discs, the discs for balancing the gait of a user, the kit comprising:

a plurality of the discs, each disc comprising a substantially rigid, circular wedge member having an planar upper surface and a planar lower surface, the upper and lower surfaces being angularly inclined with respect to each other by an angle of about 2° to about 6°, the disc being attachable to a footwear item and being rotatable through a 360° arc to enable incremental balancing adjustment for imparting proper weight distribution and balance to the user, and

wherein the discs have varying angles of inclination.

2. The balancing disc of claim 1 wherein the discs are is circular, it may be universally rotated through a 360° arc, 45 formed of a solid material which is either a rigid foam, steel, or plastic.



United States Patent [19]

Powell et al.

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[54]	RESTRAINT AND METHOD FOR THE
	IMPROVED TREATMENT OF
	RECALCITRANT PLANTAR FASCIITIS

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[21] Appl. No.: 8,499

Jan. 16, 1998 [22] Filed:

Related U.S. Application Data

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[51]	Int. Cl. ⁶	A61F 5/00
[52]	U.S. Cl 1	28/882; 602/30

[58] Field of Search 602/27-29, 30;

128/882, 892

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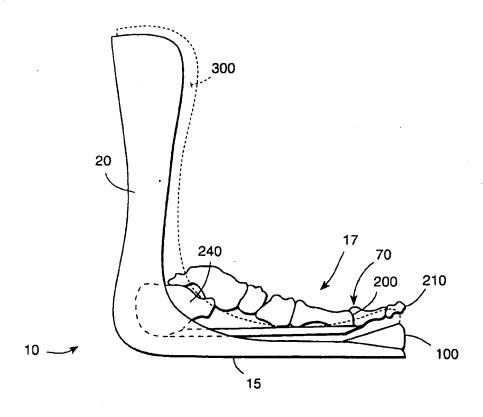
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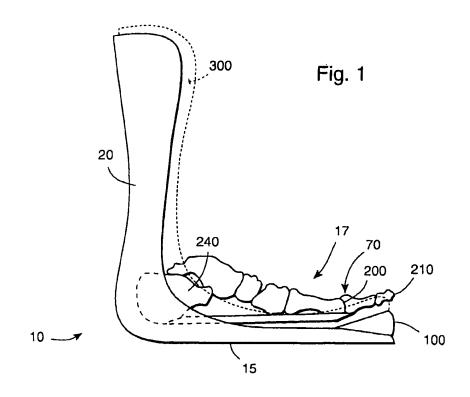
Primary Examiner-Linda C.M. Dvorak Attorney, Agent, or Firm-Hoffman, Wasson & Gitler

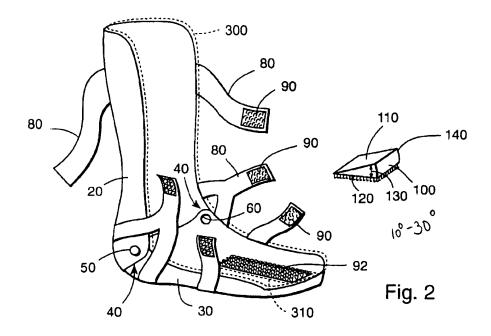
ABSTRACT [57]

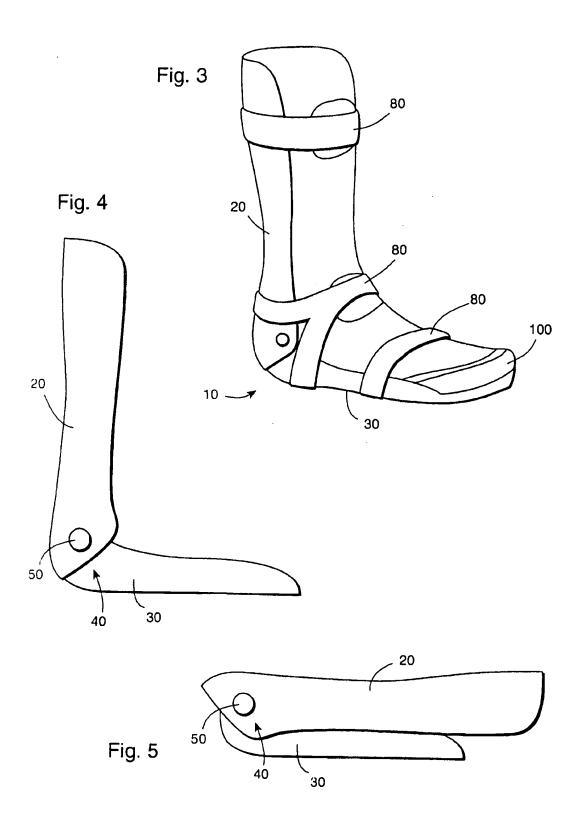
The present invention is a restraint and method for stretching the plantar fascia. A foot plate in combination with a lifting member serves to elevate the phalanges and to reduce contracture of the MTP joints. Employing a leg support shell, side railings, and straps, the present invention is able to be worn at night unobstrusively but fixedly upon the lower limb. Padding throughout the present invention ensures comfort. The user can vary the angle of dorsiflexion of the phalanges by removing and attaching various lifting members to the foot plate.

18 Claims, 2 Drawing Sheets









RESTRAINT AND METHOD FOR THE IMPROVED TREATMENT OF RECALCITRANT PLANTAR FASCIITIS

Priority is hereby claimed to Provisional Patent Appli- 5 cation Serial No. 60/035,055 filed on Jan. 17, 1997, in the names of Mark W. Powell and William R. Post.

FIELD OF THE INVENTION

The present invention is a restraint and method of treat- 10 ment for the foot. More specifically, the present invention is a restraint and method for stretching the foot's plantar fascia.

BACKGROUND OF THE INVENTION

Recalcitrant plantar fasciitis is a common and painful 15 condition which includes contractures of the plantar fascia and tightening of the muscles in the foot. It is characterized by chronic foot pain which frustrates both the patient and their treating physicians. The pain is typically at its worst in the morning which many professionals attribute to the fascia 20 contractures and muscle tightening occurring at night while the individual is sleeping.

In addition, excessively pronated or supinated feet are predisposed to plantar fasciitis. Pronation of the subtalar joint everts the calcaneus and pulls the tuberosity away from 25 the distal attachment of the plantar fascia. Excessive pronation increases the tension on the plantar fascia and its proximal attachment throughout the stance phase or gait which leads to local chronic inflammatory response.

The supinated or cavus foot has a high longitudinal arch that is rigid and less able to absorb ground reaction forces. This creates an increased demand on the plantar fascia to dissipate the resulting heightened forces exerted thereon, especially during high impact activities such as running. Plantar fasciitis can occur as unilateral involvement or bilateral involvement, where the condition occurs in one or two feet, respectively.

There are other known treatments including both surgical and nonsurgical means for relieving the symptoms of plantar fasciitis. One surgical procedure, plantar fasciotomy, also known as "open release," has been reported to have a success rate of about 40-100%. Another surgical procedure called "endoscopic release" has a success rate of approximately 85-90%. Despite the success of these surgical methods, operative intervention is generally more costly and includes a higher risk of complication than nonsurgical treatments for the patient.

Nonsurgical treatments for plantar fasciitis have been less casting, foot taping, orthotics, heel cups, activity modification, weight loss, and medications such as nonsteroidal anti-inflammatory medications and steroid injections. Occasionally, multiple treatments are prescribed for the patient. Night splints have been used, as well, to treat 55 patients with chronic recalcitrant plantar fasciitis. However, the restraints of the prior art do not provide dorsiflexion of the phalanges at the metatarsalphalangeal (MTP) joints.

Therefore, there still exists a need for a restraint which can be easily attached and removed from a foot, but is held 60 firmly in place when so attached to provide localized adjustable dorsiflexion of the phalanges at the MTP joints.

It is an object of the present invention to provide a rigid shell around the lower limb, ankle and foot.

It is a further object of the present invention to provide 65 various-sized lifting members to promote dorsiflexion of the phalanges at the MTP joints.

It is another object of the present invention to provide a series of straps for easy securing and attachment of a restraint to a foot.

It is an additional object of the present invention to provide a rigid shell around the lower limb, ankle, and foot which pivots at the ankle for greater comfort.

It is a further object of the present invention to provide a rigid shell around the lower limb, ankle, and foot which folds into a compact form for storage and transportation.

It is another object of the present invention to provide a method of employing variously sized lifting members in combination with a night restraint for rehabilitation of the plantar fascia.

It also an object of the present invention to provide a restraint and method for treatment of recalcitrant plantar fasciitis which is affordable, convenient, and fully effective in accomplishing its goals.

These and other objects of the present invention will become fully apparent from the detailed description following herein.

SUMMARY OF THE INVENTION

The present invention is a foot orthotic restraint that retains the foot and phalanges in a predetermined dorsiflexion position. The present invention acts to prevent nightly contracture of the plantar fascia and thereby effectively treat plantar fasciitis.

The restraint of the present invention is a successful low risk alternative to surgery. Wearing the restraint at night alleviates the chronic pain caused by recalcitrant plantar fasciitis, especially the pain associated with the first step taken out of bed in the morning. Additionally, the present invention provides sustained improvements in alleviating the symptoms of chronic recalcitrant plantar fasciitis. In short, the present invention is a simple and effective design that is more cost effective to the patient and health care providers than the other methods of treatment.

The restraint includes a leg support shell and a foot plate adapted to hold the patient's foot. A fixed or movable lifting member is disposed on the foot plate to induce localized dorsiflexion of the phalanges at the MTP joints which results in an optimum stretching of the plantar fascia from its origin to its insertion to relieve the symptoms of plantar fasciitis. By securing the foot as such, the restraint also prevents footdrop and the accompanying muscle tightening associated therewith.

The preferred embodiment of present invention is an successful. These treatments include physical therapy, foot 50 improved foot orthotic comprising a restraint for treating and preventing contractures of the plantar fascia and tightening of the muscles in the foot known as recalcitrant plantar fasciitis. The restraint provides dorsiflexion of the foot at the MTP joint which stretches the plantar fascia from its origin to its insertion. The plantar fascia is stretched by a lifting member positioned on the foot plate of the restraint under the phalanges such that the apex of the lifting member is at the level of the MTP joints. This position of the lifting member provides localized dorsiflexion of the MTP joints of the phalanges which results in more effective stretching of the plantar fascia. The lifting member can be adjustably positioned on the foot plate at the restraint to accommodate different foot sizes and shapes. The lifting member can be shaped however necessary to stretch the plantar fascia.

> When worn at night the restraint enables the patient's foot to resist plantar-flexion induced contracture of the plantar fascia which commonly occurs during sleep thereby reliev

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ing the symptoms of recalcitrant plantar fasciitis. This then prevents sudden reinjury when the patient first steps on the ground each day, suddenly stretching the inflammed and contracted tissue. Avoidance of this cycle of reinjury relieves symptoms and facilitates healing.

The present invention has been tested in a randomized clinical trial of patients with longstanding plantar fasciitis and has proven successful in relieving symptoms. Eighty eight percent of patients treated in this study improved and maintained their improvement at completion of the study, as reported in Foot and Ankle International, 19(1):1-9, 1998, "Effective Treatment of Plantar Fasciitis with Dorsiflexion Night Splints: A Crossover Prospective Randomized Outcome Study."

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the shell and foot plate of the present disclosure, minus straps, shown in combination with the bones of a foot.

FIG. 2 is a side elevational view of the restraint of the present invention shown with the lifting member detached.

FIG. 3 is a side elevational view of the restraint of the present invention shown strapped around a lower limb and foot.

FIG. 4 is a side view of the shell of the present invention shown in an extended position.

FIG. 5 is a side view of the shell of the present invention shown in a collapsed position.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the FIGS. 1-5, the present invention will now be described. The embodiment of the restraint 10 shown in FIGS. 1-3 includes a foot plate 15 and a leg support shell 20. The foot plate 15 has a planar surface for supporting the bottom of a patient's foot 17. Side rails 30 extend upwardly from the edges of the foot plate's planar surface forming a lower profiled side railing for retaining the patient's foot 17 on the planar surface. The leg support shell 20 is generally U-shaped and extends upwardly from the foot plate 15 for engaging the lower portion of the patient's leg.

The foot plate 15 and leg support shell 20 are attached to each other by a hinge 40 as shown in the embodiment of the invention of FIGS. 4 and 5. In alternative embodiments (not shown) the foot plate 15 and leg support shell 20 are formed as one solid piece. The hinge 40 includes a male hinge portion 50 disposed on the leg support shell 20 and a female hinge portion 60 disposed on the foot plate 15. The hinge portions 50,60 snap fit together and cooperate to enable the restraint 10 to fold freely, without binding, into a collapsed position (FIG. 5) for storing an transporting and to unfold into an opened position (FIG. 4) when in use. The low side rails 30 of the foot plate 15 enable the restraint 10 to fold into a more compact profile.

The amount of dorsiflexion or the dorsiflexion angle 70 of an ankle supported in the restraint is determined by the relative position of the foot plate 15 to the leg support shell 20 when the restraint 10 is in the opened position. In the 60 present invention, this dorsiflexion angle 70 can vary in magnitude from about 85 to 90 degrees from the plane of the foot plate, with the preferred ankle dorsiflexion angle 70 being about 95 degrees.

A plurality of straps 80 are positioned on the foot plate 15 65 and the leg support shell 20 to secure the restraint 10 to the patient's foot 17 and lower leg. The straps 80 include

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fastening strips 90, such as hook and loop type fastening elements (i.e. Velcro) and are wrapped around the patient's foot 17 and leg then fastened to hold the restraint 10 in position.

An upper surface of the foot plate 15 includes a first fastener 92, such as a hook and loop type fastening element (i.e. Velcro). The first fastener 92 is a longitudinal piece having an elongated shape, as shown in the embodiment of FIG. 2, and is generally positioned in about the middle third portion of the foot plate 15. The first fastener 92 extends from about the midsection of the foot plate 15, longitudinally, toward the distal end of the foot plate 15. It is preferable that the loop type portion of the fastening element be used as the first fastener 92 on the foot plate 15 because it is relatively softer than the hook type portion and therefore makes the restraint 10 more comfortable to wear.

The upper surface of the foot plate 15 includes a lifting member 100. In one embodiment of the present invention, the lifting member 100 has an arrow-shaped or triangularshaped cross section. The lifting member 100 has an upper surface 110, a lower surface 120, and an included angle 130 between the upper surface 110 and the lower surface 120. A second fastener 94, such as a hook and loop type fastening element, is positioned on the lower surface 120 of the lifting 25 member 100 to adjustably attach the lifting member 100 to the foot plate 15. The second fastener (not shown) on the lifting member 100 is complementary to the first fastener 92 on the foot plate 15 and is formed of the hook type fastening element since the cooperating loop type fastening element is preferably used to form the first fastener 92 on the foot plate 15. Consequently, the lifting member 100 can be positioned anywhere along the first fastener 92 and secured at that desired location on the foot plate 15 in order to fit the restraint 10 to a particular patient's foot 17. In an additional embodiment of the present invention (not shown), the lifting member 100 is fixed to the footplate 15. Further, another embodiment of the present invention has multiple lifting members (not shown).

A variety of lifting members 100 having different sizes and included angles 130 can be used interchangeably on the foot plate 15 during treatment. The included angles 130 range from about 10 degrees to about 30 degrees. Several different lifting members 100 may be used during the treatment of a single patient. The different sized and angled lifting members 100 can be made in different colors to enable the user to more easily identify its particular lifting member 100 of choice. Preferably, the lifting members 100 are made of foam having the necessary degree of firmness required to support the foot 17 in the maximum dorsiflexion position as required by the present invention.

The apex 140 of the lifting member 100 is positioned at the level of the MTP joints of the patient's foot 17. The first fastener 92 on the foot plate 15 and the cooperating second fastener (not shown) on the lifting member 100 enable the lifting member 100 to be positioned at different places on the foot plate 15, making the restraint 10 selectively adjustable to accommodate different foot 17 sizes and shapes. It also enables the lifting member 100 to be adjusted or "fine tuned" to the proper treatment position for an individual. The positioning of the lifting member 100 adjacent the MTP joints 200 provides localized dorsiflexion at the MTP joints 200 of the foot's phalanges 210 which results in true stretching of the plantar fascia 220 from its origin to its insertion since the terminal insertion of the plantar fascia 220 is on the proximal phalanx. The amount of dorsiflexion of the MTP joints 200 of the phalanges 210 is a function of the included angle 130 of the lifting member 100. For

example, a lifting member 100 having an included angle 130 of 30 degrees would result in a localized dorsiflexion of about 30 degrees to the phalanges 210.

In one preferred embodiment of the invention as shown in FIG. 1, the restraint 10 is made from polypropylene having a 5 degree angle of dorsiflexion at the ankle 240. The lifting member 100 comprises a generally 30 degree included angle 130 with the apex 140 of the lifting member 100 positioned at the MTP joints 200 of the foot 17. So by example, the restraint 10, when worn by a patient, forces an approximate 10 5 degree dorsiflexion of their foot 17 at the ankle 240, while the lifting member 100 additionally forces an approximate 30 degree localized dorsiflexion of their phalanges 210 at the MTP joints 200.

When worn at night the present invention prevents plan- 15 tarflexion induced contracture of the plantar fascia 220 during sleep, thereby preventing that first painful step in the morning. It is effective for treating patients having normal feet as well as supinated feet and pronated feet.

In other embodiments, padding 300 may be used to line 20 the interior surface of the restraint 10. The padding 300 is preferably made from a soft absorbent material with an adhesive backing. The padding 300 is adhered to the upper surface of the foot plate 15. The section of padding 300 on the foot plate 15 has a cutout 310 in the middle one third of the foot plate 15 which extends around the perimeter of the first fastener 92 so that the longitudinal piece of the first fastener 92 is not covered by the padding 300. This enables the lifting member 100 to be selectively positioned along the first fastener 92 without interference from the padding 300. The foot plate 15 can be softened with further elements (not show) for extra comfort. The padding 300 can also be placed on the inner surface of the leg support shell 20, if desired. The edges of the padding 300 are generally flush with the edges of the restraint 10.

Different types of washable padding 300 can be used with the restraint. Terry cloth is an example of one type of material. Other types of padding 300 include foams that are easily washable. The thickness of the padding 300 can vary, but 1/4 inch thickness is preferable.

A protective pad (not shown) can be used to cover the outside of the restraint 10. This outside protective pad (not shown) prevents the outer surface of the restraint 10 from chafing the patient's contralateral leg or other proximate

In another embodiment of the invention, as shown in FIG. 1, the foot plate 15 and the leg support shell 20 of the restraint 10 are integrally formed.

The restraint 10 can be made from a variety of materials 50 such as polypropylene, especially any lightweight, durable plastic strong enough to secure the foot 17 in a fixed position. The restraint 10 can be made of bright colors for decorative purposes, for example, a royal blue restraint 10 with yellow or red lifting members 100 and navy blue straps 55

To fit the restraint 10 of the present invention to a patient for treatment, a lifting member 100 of the desired included angle 130 and size is selected. The lower surface of the lifting member 100 is secured to the foot plate 15 in such a 60 way that the apex 140 of the lifting member 100 is adjacent the patient's MTP joints 200 with the thicker end of the lifting member 100 positioned toward the free distal end of the foot plate 15. The straps 80 are then positioned around the patient's lower leg and foot 17 and fastened.

Should any transient numbness occur in the patient's phalanges 210 during treatment, the lifting member 100

6 should be repositioned on the foot plate 15. The lifting member 100 is selectively adjusted by removing it from the foot plate 15, moving it a small distance from its original

position towards the distal end of the foot plate 15, and then reattaching it to the foot plate 15. If the numbness persists, the lifting member 100 should be readjusted at periodic intervals, until the numbness in the patient's phalanges 210

ceases.

In one preferred treatment plan using the restraint 10, the patient begins the first week wearing the restraint 10 at night and using a lifting member 100 with an included angle 130 of about 10 degrees. The included angle 130 of the lifting member 100 in the restraint 10 worn by the patient is increased by 10 degrees each week, so by the third week the patient has progressed to wearing a lifting member 100 with an included angle 130 of 30 degrees in the restraint 10.

In alternative embodiments of the present invention, the lifting member 100 can be an air bladder, a foam wedge, a plastazote, a pelite, or a gel. In various other embodiments of the present invention, the lifting member 100 can be placed within a pocket (not shown) within padding 300.

It is to be understood that the present invention is not limited to the embodiments described above, but encompasses any and all embodiments within the scope of the following claims.

What is claimed:

- 1. A restraint for retaining a generally planar foot in a predetermined dorsiflexion position comprising:
- a lifting member located atop said foot plate; and means for attaching said foot plate to an underside of a
- wherein said lifting member fixedly positions toes of the foot at a greater slope than the generally planar underside of the foot.
- 2. The restraint of claim 1, further comprising a leg support shell attached to and extending upwardly from said foot plate, wherein said leg support shell is formed to engage a lower leg and an ankle.
- 3. The restraint of claim 2, wherein said leg support shell is generally U-shaped.
- 4. The restraint of claim 2, further comprising a means for attaching said leg support shell to said foot plate.
- 5. The restraint of claim 4, wherein said means for 45 attaching said leg support to said foot plate is a hinge comprising a male portion and a female portion which interengage.
 - 6. The restraint of claim 2, further comprising means for attaching said leg support shell to the lower leg and the
 - 7. The restraint of claim 6, wherein said means for attaching said leg support shell to the lower leg and the ankle is at least one strap means with hook and loop fastening strips.
 - 8. The restraint of claim 2, wherein an angle of dorsiflexion between said foot plate and said leg support shell varies from about 85 degrees to 90 degrees.
 - 9. The restraint of claim 1, further comprising side rails attached to and extending upwardly from edges of said foot plate to form a lower profile side railing to retain the foot on said foot plate.
 - 10. The restraint of claim 1, wherein said foot plate is
- 11. The restraint of claim 1, wherein said means for 65 attaching said foot plate to the foot comprises at least one strap with hook and loop fastening means positioned on said foot plate to secure said foot plate to the foot.

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- 12. The restraint of claim 1, further comprising a first fastener element positioned atop and attached to said foot plate, said first fastener element in communication with said foot plate and said lifting member.
- 13. The restraint of claim 12, wherein said first fastener 5 element includes a loop fastening element.
- 14. The restraint of claim 12, wherein said first fastener element is elongated, longitudinal, and positioned in about the middle third portion of said foot plate, and extending from about a midsection of said foot plate longitudinally 10 toward a distal end of said foot plate.
- 15. The restraint of claim 1, wherein said lifting member has a triangular-shaped cross section.
- 16. The restraint of claim 1, further comprising a means for fastening said lifting member to said foot plate.

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- 17. The restraint of claim 1, wherein a plane of said lifting member and said foot plate create an angle varying from about 0 degrees to 30 degrees.
- 18. The method for treatment of recalcitrant plantar fasciitis comprising the steps of:
 - placing a lifting member on a foot plate;
 - strapping said foot plate to a bottom of a foot; and
 - varying a degree of dorsifiexion of metatarsalphalangeal joints by placing differently sized said lifting members on said foot plate;
 - wherein said lifting member fixedly positions toes of the foot at a greater slope than the generally planar underside of the foot.

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